Trinity Delta

# Scancell

Update

## Upcoming SCIB1 data could provide first proof of concept

5 September 2023

**Scancell has several key clinical data points due through to end-2024. First data will be from the Phase II trial of SCIB1 in combination with checkpoint inhibitors (CPIs) in advanced skin cancer. If successful the study will transition to the enhanced iSCIB1+ formulation that offers greater potency and broader applicability. If SCIB1 promising early data mature as hoped, then this programme could improve current outcomes. Top-line Modi-1 CPI combination data in multiple tumours are expected in 2024. The antibody platforms, GlyMab and AvidiMab, provide attractive out-licensing opportunities. Our Scancell rNPV valuation remains £300.1m, or 36.7p/share.**

| Year-end: April 30 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|
| Revenues (£m) | 0.0 | 0.0 | 5.3 | 0.0 |
| Adj. PBT (£m) | (17.7) | (11.9) | (17.6) | (24.0) |
| Net Income (£m) | (15.5) | (2.1) | (15.7) | (21.9) |
| EPS (p) | (2.28) | (0.25) | (1.93) | (2.68) |
| Cash (£m) | 41.1 | 28.7 | 17.8 | 20.2 |
| EBITDA (£m) | (8.6) | (12.6) | (13.8) | (20.2) |

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals

- **Initial SCIB1 combo data could provide first important insights** Initial data from the first stage (Cohort 1 in up to 15 patients) of the Phase II SCOPE trial of SCIB1 in combination with checkpoint inhibitors (CPIs) in advanced melanoma are expected during Q423. To validate the hypothesis that SCIB1 could have synergistic effects with doublet therapy (nivolumab + ipilimumab) nine responses are required (>55% response rate). If nine responses are achieved in fewer than 15 patients, for a higher response rate, this would suggest that SCIB1 + doublet therapy could meaningfully improve current outcomes, which would be a significant achievement, in our view.
- **Second-generation iSCIB1+ could broaden the addressable market** Scancell's AvidiMab platform has been used to enhance SCIB1, with SCIB1 limited to the c 30-40% of patients that have the appropriate human leukocyte antigen type. The enhanced second-generation programme, iSCIB1+, can address 100% of melanoma patients, broadening the target market, and is also more potent. Scancell intends to transition the SCOPE study to iSCIB1+ in combination with doublet therapy in Q423 for initial data H124. Preclinical data suggest the benefits of iSCIB1+ (performance, efficacy, and ease of admin) are a significant advance over SCIB1.
- **Data for lead Moditope vaccine, Modi-1, are expected 2024** The Phase I/II ModiFY trial of Modi-1 as monotherapy and in combination with CPIs in various challenging solid tumours is ongoing. Initial early signals of efficacy have already been observed in various monotherapy cohorts and further data are expected in 2024. The CPI combination data will be particularly important for understanding Modi-1's positioning and potential, and will be a key de-risking event.
- **Multiple catalysts could drive significant upside** Catalysts include: (1) Stage one SCIB1 doublet combination data in Q423 (9 responses from up to n=15) with stage two data (28 responses from up to n=43) expected in H124; (2) iSCIB1+ doublet combination top-line data in H124; (3) Modi-1 CPI combination data in 2024 from various cohorts; (4) partnering optionality with the GlyMab antibody platform.

| | |
|---|---|
| Price | 8.06p |
| Market Cap | £71.7m |
| Enterprise Value | £58.9m |
| Shares in issue | 818.4m |
| 12 month range | 8.05p-29.4p |
| Free float | 55.0% |
| Primary exchange | AIM London |
| Other exchanges | N/A |
| Sector | Healthcare |
| Company Code | SCLP.L |
| Corporate client | Yes |


### Company description

Scancell is a clinical-stage immuno-oncology specialist that has four broadly applicable technology platforms. Two are therapeutic vaccines, Moditope and ImmunoBody, and two are antibody based, GlyMab and AvidiMab.

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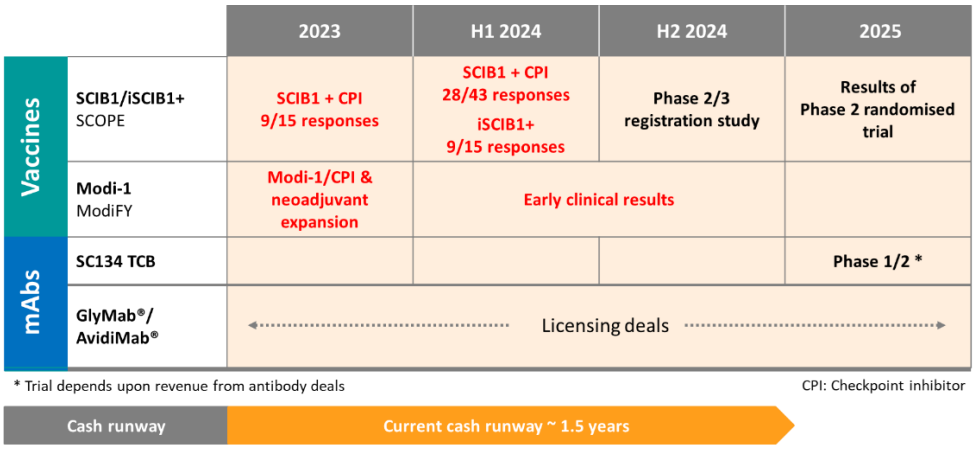
# Scancell: multiple programmes and catalysts

**Scancell is a clinical stage immunology specialist. It has two promising oncology vaccine platforms, Moditope and ImmunoBody, and two antibody technologies, GlyMab (anti-glycans) and AvidiMab, with the potential to treat many solid cancers, either as monotherapy or in combination. Modi-1, the first Moditope programme, is progressing in a Phase I/II trial targeting hard-to-treat tumours with further efficacy data due 2024. The lead ImmunoBody programme, currently SCIB1, is in a Phase II study in metastatic melanoma, with a transition to the next-generation iSCIB1+ expected later this year. The broad acting GlyMab antibodies are generating exciting preclinical data, and a first partnering deal with Genmab is already in place and further deals are possible. AvidiMab technology will be increasingly employed to enhance avidity and potency. Our risk adjusted NPV valuation for Scancell is currently £300.1m, or 36.7p/share, with significant upside from multiple upcoming catalysts.**

**Four distinct platforms with broad applicability**

Scancell has four proprietary technology platforms, which can be classified into Vaccines (Moditope and ImmunoBody) and Antibodies (GlyMab and AvidiMab). More details on each are available in our February 2023 Outlook. Scancell's pipeline of newsflow is summarised in Exhibit 1.

**Exhibit 1: Scancell pipeline key newsflow over the next three years**




Source: Scancell

## SCIB1: upcoming melanoma doublet data

**SCIB1 in combination with doublet therapy is being investigated in the SCOPE study**

The lead ImmunoBody programme is currently SCIB1, which is being developed for the treatment of advanced melanoma. The open label Phase II SCOPE study is ongoing, which is examining SCIB1 in combination with checkpoint inhibitors (CPIs). Reflecting the changes in the treatment regimen for advanced metastatic melanoma, the focus is on the combination with doublet therapy, which consists of Bristol Myers Squibb's Yervoy (ipilimumab) plus Opdivo (nivolumab).

**Hypothesis is that SCIB1 with CPIs can act synergistically to improve outcomes**

The study rationale is that the SCIB1 ImmunoBody vaccine primes an immune response against the tumour, whilst the CPI reduces the immune-suppressant effect seen in the tumour microenvironment, which together could increase the number of patients who respond to treatment. Preclinical studies show a strong

synergistic effect when SCIB1 is combined with a relevant CPI (c 85% response rates in animal models).

**Doublet therapy response rates are around 48-58%...**

For context, and with the caveat of cross trial comparison limitations, the FDA approved label for Opdivo in combination with Yervoy, based on the CHECKMATE-067 study, cites an overall response rate (ORR) of 50% for the combination (based on a primary analysis with nine months of follow-up) vs 40% for Opdivo monotherapy and 14% for Yervoy alone. The ORR for the combination is 58% in longer-term CHECKMATE-067 data at both five and 6.5 years. Real-world data (at median follow-up of 12 months) reports an ORR of 48%. The ORRs achieved with doublet therapy are the highest observed in advanced melanoma.

**...so anything above this would be impressive**

Top-line data from the first stage (Cohort 1) of the SCOPE study, examining SCIB1 in combination with doublet therapy, are expected during Q423. This cohort will recruit up to 15 patients and a >55% response rate (ie nine responses) is required to validate the study hypothesis before progressing to the second stage. If nine responses are achieved in fewer than 15 patients, this would represent an ORR that appears higher than ORRs observed with doublet therapy alone, as described above. Hence, this could translate to improved outcomes for patients which would be a significant achievement, in our view.

The second stage will recruit up to a further 28 patients (for a total of up to 43 patients across both stages). The aim is to achieve 19 responses (ie 28 responses in total), which would represent at least a 65% response rate (28/43). This would demonstrate that SCIB1 in combination with doublet therapy exceeds currently achievable ORRs. Recruitment is expected to be complete by the end of 2023 with data around three months later ie during H124. If response rates of these magnitudes are achieved, then this could generate partnering interest, in our view.

**Positive SCOPE data in H124 could lead to the start of a registrational trial in H224**

The plan is to transition the SCOPE study to the enhanced, second-generation iSCIB1+. A repeat of Cohort 1 using iSCIB1+ in combination with doublet therapy could start by YE23 for top-line data H124e. If expanded data from these cohorts are positive, then a potentially registrational Phase II/III trial could be initiated.

## Modi-1: combination data in challenging cancers in 2024

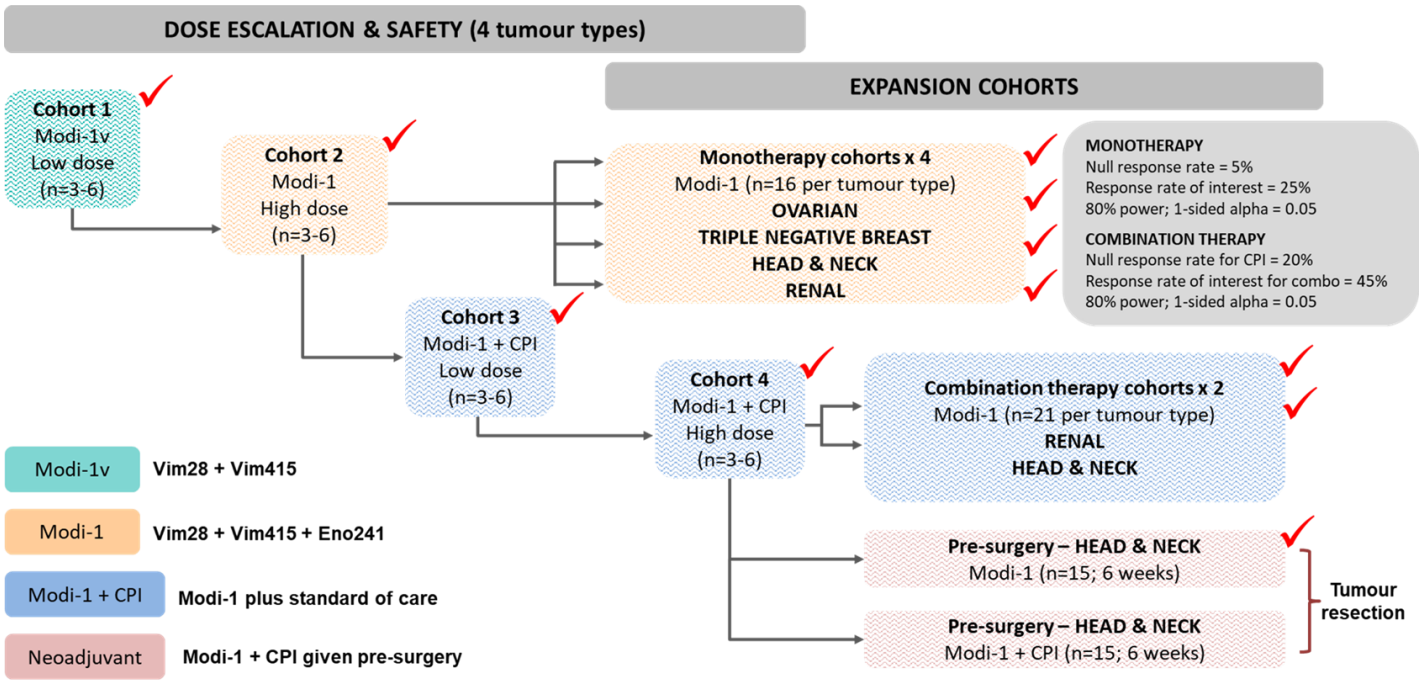
**Phase I/II basket design to maximise understanding**

The Phase I/II ModiFY study of Modi-1 is a two stage trial with an initial dose escalation and safety phase, already successfully completed, followed by a number of specific expansion cohorts that explore Modi-1 in a variety of hard-to-treat solid tumours as monotherapy, in combination with CPIs, as well as in the neoadjuvant (pre-surgical) setting. These include triple-negative breast cancer (TNBC), ovarian cancer, head & neck cancer, and renal cancer. A total of up to 138 patients across up to 20 UK sites will be treated. An overview of the trial design is shown in Exhibit 2.

**Initial safety phase complete and recruitment into expansion cohorts is ongoing**

The initial dose escalation and safety phase has been successfully completed with Modi-1 injections well tolerated at both low and high doses as monotherapy and in combination with a CPI. Recruitment into the ovarian cancer monotherapy cohort is complete, whilst recruitment into other expansion cohorts (monotherapy, combination with CPI, and neoadjuvant settings) is ongoing.

## Exhibit 2: Modi-1 Phase I/II clinical trial design




Source: Scancell Note: CPI = checkpoint inhibitor

**Early monotherapy data are encouraging**

The ovarian cancer monotherapy expansion cohort has completed recruitment of 16 patients. All patients had failed prior treatment and had actively progressing disease. The disease control rate was 44% (7/16) following treatment with Modi-1 (stable disease for at least eight weeks), with some patients experiencing disease stabilisation for four or more months. In other monotherapy expansion cohorts, eight patients have received a full dose of Modi-1, with the following results:

- One TNBC patient remains on trial with stable disease beyond 8 weeks
- One head & neck patient achieved a partial response and remains on study at week 37.

**CPI combination data will be key in defining Modi-1's clinical and commercial positioning**

Recruitment into the key CPI combination expansion cohorts has been approved and is underway, with data expected during 2024. These are focused on Modi-1 in combination with a CPI in head & neck and renal cancers, and in the neoadjuvant (pre-surgery) setting in head & neck cancer.

## GlyMabs: partnering optionality

**Genmab deal provides validation of GlyMab platform and an example of the partnering optionality potential**

Scancell has built a pipeline of differentiated broad acting anticancer GlyMab antibodies, and currently has five in early-stage development. In October 2022 Genmab effectively validated the GlyMab platform when it acquired the rights to develop one of these preclinical antibodies, SC129, into multiple novel therapeutic product modalities for all disease areas, excluding cell therapy applications (which are retained by Scancell). The Genmab deal, which could generate up to a maximum of $624m in milestones if all the modalities were to be progressed, plus royalties, is an example of the partnering optionality within the GlyMab pipeline. We expect the remaining programmes, and other undisclosed ones in earlier stages of preclinical development, will be progressed to preclinical validation points and then also be partnered for further clinical development.

## Exhibit 3: Summary of financials

| Year-end: April 30 £'000s | 2020 | 2021 | 2022 | 2023E | 2024E |
|---|---|---|---|---|---|
| **INCOME STATEMENT** | | | | | |
| **Revenues** | **0** | **0** | **0** | **5,271** | **0** |
| Cost of goods sold | 0 | 0 | 0 | 0 | 0 |
| **Gross Profit** | **0** | **0** | **0** | **5,271** | **0** |
| R&D expenses | (4,667) | (6,406) | (9,477) | (14,504) | (15,144) |
| General and administrative expenses | (2,115) | (3,346) | (4,787) | (5,266) | (5,792) |
| **Underlying operating profit** | **(6,782)** | **(9,752)** | **(14,264)** | **(14,499)** | **(20,936)** |
| Other revenue/expenses | 0 | 918 | 965 | 0 | 0 |
| **EBITDA** | **(6,739)** | **(8,585)** | **(12,559)** | **(13,842)** | **(20,249)** |
| **Operating Profit** | **(6,782)** | **(8,834)** | **(13,299)** | **(14,499)** | **(20,936)** |
| Interest expense | 14 | (1,648) | (2,878) | (2,220) | (3,041) |
| Other financing costs/income | 0 | (6,323) | 12,409 | (910) | 0 |
| **Profit Before Taxes** | **(6,768)** | **(16,805)** | **(3,768)** | **(17,628)** | **(23,977)** |
| **Adj. PBT** | **(6,768)** | **(17,723)** | **(11,899)** | **(17,628)** | **(23,977)** |
| Current tax income | 1,262 | 1,328 | 1,703 | 1,895 | 2,031 |
| Cumulative preferred stock dividend | 0 | 0 | 0 | 0 | 0 |
| **Net Income** | **(5,506)** | **(15,477)** | **(2,065)** | **(15,733)** | **(21,947)** |
| | | | | | |
| **EPS (p)** | **(1.21)** | **(2.28)** | **(0.25)** | **(1.93)** | **(2.68)** |
| **Adj. EPS (p)** | **(1.21)** | **(2.42)** | **(1.25)** | **(1.93)** | **(2.68)** |
| **DPS (p)** | **0.00** | **0.00** | **0.00** | **0.00** | **0.00** |
| Average no. of shares (m) | 456.2 | 678.6 | 815.2 | 815.9 | 818.4 |
| | | | | | |
| *Gross margin* | *N/A* | *N/A* | *N/A* | *100%* | *N/A* |
| | | | | | |
| **BALANCE SHEET** | | | | | |
| **Current assets** | **5,208** | **44,668** | **32,362** | **21,156** | **23,500** |
| Cash and cash equivalents | 3,575 | 41,110 | 28,725 | 17,766 | 20,160 |
| Accounts receivable | 371 | 968 | 647 | 400 | 350 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 1,262 | 2,590 | 2,990 | 2,990 | 2,990 |
| **Non-current assets** | **3,610** | **4,390** | **6,159** | **5,702** | **5,215** |
| Property, plant & equipment | 195 | 975 | 2,744 | 2,287 | 1,800 |
| Other non-current assets | 0 | 0 | 0 | 0 | 0 |
| **Current liabilities** | **(1,091)** | **(2,295)** | **(2,452)** | **(3,980)** | **(24,476)** |
| Short-term debt | 0 | 0 | 0 | 0 | (20,000) |
| Accounts payable | (1,041) | (2,087) | (2,137) | (3,665) | (4,161) |
| Other current liabilities | (50) | (208) | (315) | (315) | (315) |
| **Non-current liabilities** | **(79)** | **(27,278)** | **(17,959)** | **(19,909)** | **(19,659)** |
| Long-term debt | 0 | (27,215) | (17,103) | (19,303) | (19,303) |
| Other non-current liabilities | (79) | (63) | (856) | (606) | (356) |
| **Equity** | **7,648** | **19,485** | **18,110** | **2,969** | **(15,420)** |
| Share capital | 38,853 | 65,834 | 65,834 | 65,977 | 65,977 |
| Other | (31,205) | (46,349) | (47,724) | (63,008) | (81,397) |
| | | | | | |
| **CASH FLOW STATEMENTS** | | | | | |
| **Operating cash flow** | **(4,772)** | **(7,803)** | **(10,730)** | **(9,900)** | **(17,245)** |
| Profit before tax | (6,768) | (16,805) | (3,768) | (17,628) | (23,977) |
| Non-cash adjustments | 22 | 8,553 | (8,101) | 4,786 | 4,828 |
| Change in working capital | 143 | 449 | 372 | 1,775 | 545 |
| Interest paid | 0 | 0 | (537) | (537) | (537) |
| Taxes paid | 1,831 | 0 | 1,304 | 1,703 | 1,895 |
| **Investing cash flow** | **(13)** | **(741)** | **(1,264)** | **(42)** | **(111)** |
| CAPEX on tangible assets | (27) | (744) | (1,268) | (200) | (200) |
| Other investing cash flows | 14 | 3 | 4 | 158 | 89 |
| **Financing cash flow** | **3,800** | **46,079** | **(391)** | **(107)** | **19,750** |
| Proceeds from equity | 3,827 | 22,727 | 0 | 143 | 0 |
| Increase in loans | 0 | 23,506 | 0 | 0 | 20,000 |
| Other financing cash flow | (27) | (154) | (391) | (250) | (250) |
| **Net increase in cash** | **(985)** | **37,535** | **(12,385)** | **(10,959)** | **2,394** |
| Cash at start of year | 4,560 | 3,575 | 41,110 | 28,725 | 17,766 |
| **Cash at end of year** | **3,575** | **41,110** | **28,725** | **17,766** | **20,160** |
| **Net cash at end of year** | 3,575 | 13,895 | 11,622 | (1,537) | (19,143) |

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals.

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